



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/311,996	05/14/99	VAISBERG	E 19681-4

020350 HM22/0929
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EXAMINER

SIU, S

ART UNIT	PAPER NUMBER
1631	3

DATE MAILED: 09/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/311,996	Applicant(s) VAISBERG ET AL.	
	Examiner Stephen C Siu	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-17 is/are allowed.
- 6) ☒ Claim(s) 1-12 and 18-48 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
 1. ☐ received.
 2. ☐ received in Application No. (Series Code / Serial Number) ____ .
 3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 16) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

There are two claims numbered "6". Under Rule 126, claim 6 (second occurrence) has been renumbered to claim 7.

Specification

The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

The disclosure is objected to because of the following informalities: the disclosure contains blanks on the first page.

Appropriate correction is required.

Claim Objections

Claim 37 is objected to because of the following informalities: there are 2 periods at the end of the sentence. Appropriate correction is required.

Claim 45 is objected to because of the following informalities: "degree of presence is multiple..." appears to be missing an article before the word "multiple". Appropriate correction is required.

Claim 48 is objected to because of the following informalities: there is an invalid space within the word "wherein". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 7, and 40-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 7 recite "said values" which lacks antecedent basis.

Claim 6 recites "amino acid letter" which is confusing because it is not clear what is meant by a "letter" in this context.

Claim 40 and dependent claims 41-45 recite "said morphometric value" which lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Biodx (WO 97/45730, 12/4/97, PTO-1449 reference AC).

Biodx (WO 97/45730, 12/4/97) discloses a computer-implemented method (page 12, line 3) for analyzing cells wherein cells containing reporter molecules are scanned with a fluorescence microscope (i.e. "manipulated"), converting the optical information into digital data (i.e. "capturing an image"), and utilizing the digital data to determine the distribution, environment or activity (i.e. "determining a descriptor") of the labeled reporter molecules in the cells (page 11, line 19 – page 12, line 1), including a

computerized method for processing, displaying (page 12, lines 2-5) and storing the data (i.e. "populating a database"). Inherent in a teaching of a "computer system" is storage medium for "holding the codes".

Claims 1-5, 8-12, 17-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Pauwels (Journal of Pharmacological and Toxicological Methods, Vol.37, March 1997, pages 105-115, PTO reference AE).

Pauwels (Journal of Pharmacological and Toxicological Methods, Vol.37, March 1997, pages 105-115) teaches a method comprising exposing neoplastic cell lines with drugs of various pharmacological classes (i.e., "manipulating cells in various stages of the cell cycle"), monitoring drug-induced modifications by means of a digital cell image analysis of stained nuclei (i.e., "capturing an image") to create databases (page 106, col.1, lines 4-6), submitting numerical data quantitatively describing chromatin patterns to multivariate analysis with canonical transformation of the data (i.e., determining a "descriptor" from the image and populating a database) – see abstract. In the image analysis, parameters are derived including mean optical density, variance, skewness and kurtosis indices, etc. for analysis of chromatin (page 107, col.2, paragraphs 3 and 4). Inherent in a computer is a computer readable storage medium for "holding the codes". The method involves analysis of mechanism of action of anticancer drugs on neoplastic cell lines (i.e., properties comprise "applying a chemical factor", "applying a biological factor", "toxicity", "specificity against a subset of tumors", "mechanism of chemical activity", "mechanism of biological activity", "a mechanism of action", "a

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structure", "at least one of a plurality of adverse biological effects", "at least one of a plurality of adverse biological pathways", "at least one of a plurality of adverse clinical effects", "at least one of a plurality of cellular availability", "at least one of a plurality of pharmacological properties", "pharmacodynamic properties", or "selected from clinical uses and indications, human and veterinary diagnostic uses and tests, or human and veterinary prognostic uses and tests" and "manipulation" comprising "a temporal factor" or "applying a nuclear factor" (chromatin)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pauwels (Journal of Pharmacological and Toxicological Methods, Vol.37, March 1997, pages 105-115, PTO-1449 reference AE) in view of Weinstein (Science, Vol.275, 17 Jan 1997, pages 343-349, PTO-1449 reference AJ).

Pauwels teaches a method comprising exposing neoplastic cell lines with drugs of various pharmacological classes as above.

Pauwels does not teach the use of a gene expression profile.

Weinstein teaches the use of a gene expression profile in screening a panel of cancer cell lines.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the computer-implemented method of Pauwels and to further analyze gene expression profiles as effects on cells by external stimuli because doing so would have provided information useful in generating clinically active agents as per the teachings of Weinstein. Thus, one of ordinary skill in the art would have been motivated to perform the invention as claimed with a reasonable expectation of success.


Conclusion

Claims 1-12 and 17-48 are rejected. Claims 13-16 are allowable.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stephen Siu, whose telephone number is (703) 308-7522. The Examiner can normally be reached from 7:00 a.m. to 3:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 308-0294. Please call the Examiner at (703) 308-7522 before the transmission to expedite delivery of the fax. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephen Siu


JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER